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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/673,643

10/31/2000

Masayuki Yokoi

M&M-031-USA

7093

7590

02/27/2002

Townsend & Banta  
Suite 500  
1225 Eye Street NW  
Washington, DC 20005

EXAMINER

GRUN, JAMES LESLIE

ART UNIT

PAPER NUMBER

1641

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/673,643**

Applicant(s)  
**YOKOI et al.**

Examiner  
**James L. Grun, Ph.D.**

Art Unit  
**1641**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 9 Nov 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, and 9-16 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, and 9-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 November 2001 is acknowledged and has been entered. Claim 4 has been cancelled by applicant's submission. Claims 1-3, 5, 6, and 9-16 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. When formal drawings are submitted, the draftsman will perform a review. Direct any inquiries concerning drawing review to the Drawing Review Branch at (703) 305-8404.

The specification is objected to and claims 1-2, 5-6, 9-11, and 13 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that these claims contain subject matter

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which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Particularly, the invention commensurate with that as instantly claimed. As set forth, absent further description and guidance from Applicant, one would not be assured of the ability to practice the invention as claimed with an enzyme substrate which is also sterically inhibited from interacting with enzyme on the agglutinated solid phase. Signal modification would not be related to the action of the enzyme inhibitor in such a case. In claim 1 the examiner would suggest: --(b) an enzyme inhibitor for reacting with and inhibiting activity of said enzyme, said enzyme inhibitor being in a free state uncoupled to an antigen or antibody and being increasingly hindered from reacting with said enzyme when said insoluble carrier is increasingly aggregated; and ( c ) a substrate for the enzyme capable of producing an optically detectable indication of reaction with the enzyme, wherein said substrate is not hindered from reacting with said enzyme when said enzyme is unreacted with said enzyme inhibitor when said insoluble carrier is increasingly aggregated; said components (a) - ( c ) being maintained...-- . Moreover, for the reasons of record, one would not be assured of the ability to practice the invention with “plural different combinations in type of said antibody or antigen, enzyme and substrate” as instantly claimed if different antibody or antigen components were bound to the same carrier as disclosed.

Applicant's arguments filed 09 November 2001 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's implication to the contrary, the schematics of the desired reaction principles do not allay the examiner's concerns of record.

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Applicant urges that the claimed "plural different combinations" involve the different reagents coupled to different carriers. This is not found persuasive because applicant's argument is drawn to a limitation not found in the claims. The examiner would also note, in view of the reagents taught in Example 4 on pages 41-44 of the specification, that the disclosure of the invention is not necessarily limited as argued to separate particle populations having the different combinations thereon.

Claims 2, 3, and 11-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2 it is not clear how the multiple reagents of the claim further limit "an immunoassay reagent" comprising components which are maintained separate and apart as claimed in the independent claim.

In claims 11, the interrelationships of the components are not clear because it is not clear that the enzyme reaction contributes anything to the absorbance.

In claims 3 and 12-16, the interrelationships of the components are not clear because it is not clear how components ( b ) and ( c ) contribute anything to the absorbance change or measurement, or to quantitative determination.

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Applicant's arguments filed 09 November 2001 have been fully considered but they are not deemed to be persuasive. Applicant urges that claim 2 further limits the reagent of claim 1 by providing components b and c mixed. This is not found persuasive for the reasons of record because a mixture of components does not properly further limit components which are maintained separate and apart. Notwithstanding applicant's argument to the contrary, the schematics of the desired reaction principles do not allay the examiner's concerns of record regarding claims 11 and 16 because there is nothing in the claims to clarify the relationships.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.

  
James L. Grun, Ph.D.  
February 25, 2002

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/641